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Ms. Kimberly Topper  
Center For Drug Evaluation & Research  
Food and Drug Administration  
5600 Fishers Lane  
Rockville, Maryland 20857  
Fax: (301) 827-6801

Dear Ms. Topper:

One of the Purdue Frederick representatives with whom I have frequent contact has given me an invitation to the June 14<sup>th</sup> and 15<sup>th</sup> meeting regarding opioid analgesics. While I am unable to attend this meeting, I would like to submit to you a summary of my experience with opioids.

I am an anesthesiologist practicing pain management exclusively. I have done this for the past seven years. I am part of a four-person pain management practice in Grand Rapids, Michigan. The bulk of our patient population suffers from chronic, non-malignant pain. We practice a comprehensive approach to pain management, working with physical therapists, psychotherapists, and other allied professionals. We spend quite a bit of time in non-procedural pain management consultations.

Our experience with opioids, particularly of long acting variety, is fairly vast. Each doctor within the practice has hundreds of patients taking these medications. In addition to Oxycontin, we prescribe Duragesic, Kadian, Methadone, etc. We have a strict narcotic agreement and we hold all of our patients to it to the letter.

When I first started practicing, I was somewhat flexible in addressing patient compliance issues. What we found is that this flexibility, however well intentioned, leads one open to manipulation by a small part of the patient population intent on misusing opioids. I could estimate that, during these days of greater flexibility, perhaps 6-8% of the patients we saw took advantage of our flexibility.

Perhaps two years ago, we began to see that this behavior, among a certain patient type was fairly predictable. We then became very strict, almost overnight, in our adherence to the signed narcotic agreement.

We found that, between the four of us, perhaps 20 patients continued to violate their agreement, and were hence discharged from the practice with appropriate referrals to addictionologist and drug treatment centers. A larger number of patients quickly fell into line regarding their compliance to the narcotic contract.

We had a break in at our office earlier this year. A scheduled prescription pad was stolen, and forged prescriptions for Oxycontin were written and distributed. Thanks to rapid, aggressive intervention by detectives with Michigan State Police in Ionia, the perpetrators were apprehended. They were not patients. They did have association with a small number of our patients. It became apparent that perhaps 30-40 people in the Grand Rapids, Michigan area were involved in related scams to obtain narcotics for abuse. Thankfully, most of these individuals are now in the criminal justice system.

Aside from this unfortunate incident, I have been frankly pleasantly surprised by the degree to which our chronic pain patients comply with the signed narcotic agreement. Our experience essentially falls into line with what Steve Pasik generated in his study through Janssen Pharmaceuticals. His study indicated that fewer than 4% of chronic, non- malignant pain patients end up in abusive relationships with prescribed medications. This is contrasted to his finding that 12-15% of the population at large abuses recreational drugs or alcohol with regularity. It would seem, strangely enough, that chronic pain patients are actually more likely to avoid abuse than the general public. Perhaps this is a reflection of their involvement with a signed narcotic agreement. Perhaps this is a reflection of their understanding that the pain relief they obtain from properly prescribed narcotics is a privilege that they must support with appropriately responsible action.

In summary, I must say that I feel the press coverage of the abuse of Oxycontin and other long acting opioids is quite biased and frankly sensational in nature. It seems to be a popular trend in this country to dodge issues of personal responsibility and point fingers of blame away from oneself. The press feeds this trend, as do many of the politicians we see at federal and state levels. I discuss with my patients their responsibilities, and I challenge them to behave in a fashion that essentially matches the principals upon which the United States of America were founded. As a doctor, I have never been comfortable behaving in a patriarchal or monarchal fashion. I have never felt comfortable picking and choosing who gains access to something that I, as a physician, could provide myself or my family. I know I certainly become quite enraged when I see people attempting to restrict my rights and privileges simply because a select irresponsible segment of the population has chosen to abuse the same.

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As I tell my patients, I do not perceive myself as a gatekeeper, parent, or official drug restricter. Rather, I see myself as a coach and an advisor. I purposely set the bar high, and expect patients will rise to reach it. Opioids are, without a doubt, the strongest pain relievers we have available at this time. Like so much else in life, including parenting, automobile ownership, firearms ownership and homeownership, use of these medications comes with a high price in terms of personal responsibility. There are plenty of countries where use of opioids to treat chronic pain, and indeed many of the privileges mentioned in the previous sentence that we more or less take for granted, are in fact not options. I could never comprehend living under such circumstances, I would not ask my patients to do so unless they clearly demonstrated an inability to behave responsibly.

Thank you for your time and consideration.

Sincerely,

A handwritten signature in black ink, appearing to read 'T. M. Basch, M.D.', written in a cursive style.

Thomas M. Basch, M.D.

TMB/as